

REMARKS

Claims 20, 21 and 23-38 are under examination. Claims 20, 23, 29, and 31 are amended to more clearly reflect the claimed subject matter. These claim amendments are supported in the specification at page 3, lines 14-15. No new matter is added by this amendment.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Written Description

The Examiner has rejected claims 23-27 as allegedly failing to meet the written description requirement of 35 U.S.C. § 112, first paragraph. The Examiner contends that the genus of BMPs recited in the claims is not adequately described. Applicants disagree.

Contrary to the Examiner's assertion, Applicants have provided the "structural or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure . . . sufficient to show the applicant was in possession of the claimed genus." (O.A. of 3/7/07, p. 3-4.) Possession may be shown by describing the technology that is sought to be patented (Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005)), and does not require the Applicants to spell out every detail of the invention in the specification (Falkner v. Inglis, 448 F.3d 1357 (Fed. Cir. 2006)). Applicants are not required to disclose what is known in the art, and in fact, the Federal Circuit has specifically held that "[i]t is manifestly impractical for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure

teaches those skilled in the art what the invention is and how to practice it. ” In re Grimme, 398 F.2d 867, 871 (C.C.P.A. 1962).

Applicants have clearly described and exemplified both what the invention is and how to practice it, in other words, the technology sought to be patented. The claimed invention is a method for regeneration of articular cartilage by administering an osteochondral graft coated with a BMP. BMPs are a highly homologous family of proteins with similar activities, and 16 members of the genus of BMPs are fully described in the specification. The sequences and functions of these 16 BMPs were known in the art and need not be recited again in the instant application. Furthermore, the functional similarities of all BMP family members were known in the art, and are described in the specification again at page 3, lines 3-4, which states that these proteins all have osteogenic and chondrogenic activities.

The Federal Circuit has held that a broad description of functional groups, broad classes of polyfunctional compounds, thirty-three specific compounds, and fifteen working examples was legally sufficient to support a claim to a genus of polyfunctional organic compounds. As the rationale for its finding, the court relied on the fact that “the invention” was not the polyfunctional organic compound, but instead was the combination of this class of compounds with a novel polyisocyanate. In re Grimme, 398 F.2d 867, 871 (C.C.P.A. 1962). This analysis parallels Applicants’ situation. Applicants’ invention is not the BMPs per se. Instead, the invention arises from the combination of a BMP with an osteochondral graft for treatment of articular cartilage defects. Accordingly, as with the polyfunctional organic compounds in Grimme, the BMPs are adequately described in and supported by the specification.

Applicants submit that a claim to the genus of BMPs is fully supported by the specification. However, in order to expedite allowance of the claims, Applicants have amended the claims to recite specific members of the BMP family. These BMPs are clearly defined in the specification at page 3, lines 14-15 and 18-20 and are known to possess cartilage-inducing activity (see, e.g., U.S. Patent Nos. 5,108,922; 5,013,649; 5,116,738; 5,106,748; 5,187,076; and 5,141,905, all cited in the specification as filed). Indeed, evidence of the cartilage-inducing activity of these proteins is also present in the reference cited by the Examiner, van Beuningen et al. (i.e. reference U cited as “Henk et al.”, *Osteoarthritis and Cartilage* 6:306-17 (1998)), which states that in addition to BMP-2, “[o]ther members of the BMP family, like BMP-3, BMP-4, BMP-5, and BMP-7 are also able to induce new cartilage and bone in vivo” (see first column, page 314 of van Beuningen et al. *Osteoarthritis and Cartilage* 6:306-17 (1998)).

Accordingly, claims 23-27 are clearly described in the specification in compliance with 35 U.S.C. § 112, first paragraph. Therefore, Applicants respectfully request that this rejection be withdrawn.

Enablement

The Examiner has rejected claims 23-27 as allegedly lacking enablement under 35 U.S.C. § 112, first paragraph. The Examiner contends that the specification does not provide sufficient guidance to practice the invention with BMPs other than BMP-2, BMP-12, and BMP-13. Applicants disagree.

The invention relates to methods of regenerating articular cartilage by administering an osteochondral graft coated with a BMP. The majority of BMP family

members have been shown to possess cartilage-inducing activity. Accordingly, one of skill in the art would have recognized, at the time of the invention, that any claimed BMP would provide the necessary chondrogenic activity. Applicants have demonstrated, for the first time, that the treatment of an osteochondral graft with BMP prior to implantation results in improved integration of the graft with the recipient site. Once this unexpected feature was demonstrated with one BMP, it requires absolutely no undue experimentation to perform the same method with other BMPs, particularly those that are *known* to have osteogenic and chondrogenic activity.

Accordingly, Applicants submit that claims to the entire genus of BMPs are enabled. Nevertheless, in order to expedite allowance of the claims, and not in acquiescence to the Examiner's rejection, Applicants have amended the claims to recite the use of the specific BMPs 2, 4, 5, 6 and or 7. These BMPs, as discussed above, were all known to possess osteogenic and chondrogenic activity at the time of the invention (van Beuningen et al., *Osteoarthritis and Cartilage* 6:306-17 (1998)). Therefore, no undue experimentation would be required to use the recited BMPs in the methods of the invention. Therefore, Applicants respectfully request reconsideration, and withdrawal of the rejection.

REJECTION UNDER 35 U.S.C. § 102

The Examiner has rejected claims 20-21, 23, 29-33, and 38 as allegedly anticipated by the van Beuningen et al., *Osteoarthritis and Cartilage* 6:306-17 (1998) reference (i.e. reference U, cited as "Henk et al.") under 35 U.S.C. § 102(b). The Examiner contends that van Beuningen et al. teaches a method of using BMP-2 to

repair cartilage and that it is intended to be used on joints and grafts. Applicants respectfully traverse this rejection for the reasons that follow.

The pending claims recite methods of repairing cartilage by administering an osteochondral graft coated with a BMP. The van Beuningen et al. reference does not teach or suggest the use of an osteochondral graft, which is a specialized type of tissue graft. Indeed, despite the Examiner's assertion to the contrary, van Beuningen et al. does not teach the use of a graft at all, let alone an osteochondral draft. Osteochondral grafts are a unique source of naturally integrated tissue formed in the body by the development of both bone and cartilage tissues, and thus comprise elements of both bone and cartilage. An osteochondral graft, as known in the art, is a living tissue graft derived from the cartilage-bone interface characterized by the natural transition of bone tissue to cartilage tissue. The van Beuningen et al. reference does not teach or suggest such a graft. Rather, the van Beuningen et al. reference's teachings are limited to the injection of BMP-2 directly into joints to increase proteoglycan synthesis. In contrast, Applicants claim a method of repairing articular cartilage by administering an osteochondral graft coated with a BMP.

Accordingly, the van Beuningen et al. reference (i.e. reference U cited by the examiner as "Henk et al.") does not teach all the limitations of the claimed invention and, therefore, does not anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the claims are in good condition for allowance, and respectfully request prompt reconsideration and acknowledgement to this effect. No fees are believed to be due at this time, however please grant any extensions of time required to enter this response, and charge any additional fees, or credit any overpayments, to our deposit account 06-0916.

Should the Examiner have questions regarding this application, she is invited to contact the undersigned attorney for the Applicant at 617-452-1640.

Respectfully submitted,

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By: _____



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